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| 10/635,439 | 08/07/2003 | Ross Clark | K-2187/1 | 8576 |

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| EXAMINER | |
|---|---|
| SOROUSH, ALI | |

| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/635,439 | CLARK, ROSS | |
| | Examiner | Art Unit | |
| | Ali Soroush | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *7 and 13-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Acknowledgement of Receipt*

Applicant's response filed on 03/14/2007 to the Office Action mailed on 09/14/2006 is acknowledged.

### *Status of Claims*

Claims the applicant withdraws 13-27 and claim 7 is withdrawn as being directed to unelected subject matter. Claims 1 and 8 have been amended. Therefore claims 1-6 and 8-12 are currently under consideration for patentability.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended claims to include the limitation that the film have "a thickness of about **100** micrometers or less", however there is no support for this in the specification. The specification recites that the film can have a thickness ranging from "**about 10 to about 200 micrometers, and preferably about 25 to 75 micrometers**". (See page 9, Lines 1-2). Further the examples do not

indicate any films being formed that have a thickness of about 100 micrometers. For the foregoing reasons the claims fail to comply with the written description requirement.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Rejection of claims 1, 2 5, 6, 8, 9, and 12 under 35 U.S.C. 103(a) as being unpatentable over Leung et al. (US Patent Application 2001/0022964 **is withdrawn** in light of the amendment submitted with the aforementioned response.

***New Grounds of Rejection***

2. Claims 1-6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung et al. (US 2001/0022964) in view of Hoagland (US 5,919,574).

***Applicant Claims***

Applicant claims a film and/or a film composition comprising pectin with an intrinsic viscosity of about 2.5 dl/g or less and at least one bioactive agent such as a flavoring agent for consumption and delivery of a bioactive agent. Wherein, the pectin is either high or low methyl ester pectin.

***Determination of the Scope and Content of the Prior Art (MPEP § 2141.01)***

Leung et al. teaches fast dissolving orally consumable films. The film comprises at least one water-soluble polymer and the essential oils as antimicrobial/flavoring agents, and can further compromise water, additional antimicrobial agents, film-forming agents, flavoring agents include those known to the skilled artisan such as natural and artificial flavorings, etc. (title; column 4, paragraph 34; and column 6, paragraph 52). Leung et al. teaches a number of water-soluble polymers including pullulan and pectin. Leung et al. does not distinguish between the polymers, which suggests that in Leung et al.'s context the polymers in the list presented are equivalent in function at least in Leung's invention. Therefore, Leung et al. makes obvious the use of about 40 to about 80 wt% of pectin in the film composition which falls within the instant amount of pectin ranging from about 20 to about 80% by weight pectin in the film. With regard to the intrinsic viscosity of pectin of about 2.5 dl/g and about 1.8 dl/g or less, Leung et al. is silent to the intrinsic viscosity of pectin which suggests that a broad range of pectin viscosities would work possibly even in the

narrower viscosities recited in the claims. In the absence of a showing of the criticality of the narrower intrinsic viscosity disclosed in the instant invention, Leung makes obvious the instant intrinsic viscosity. In addition, the intrinsic viscosity of pectin being used in Leung et al. cover the instant amount (2.5 dl/g or less) since through routine experimentation of Leung et al.'s invention can lead an artisan arriving at the instant intrinsic viscosity being used. One would have been motivated to do this in order to develop a composition that would have been effective as an orally soluble film while also maintaining its film like structure prior to use.

***Ascertainment of the Difference Between Scope of the Prior Art and the Claims (MPEP §2141.012)***

Leung et al. lacks the teaching of the intrinsic viscosity of pectin. Also, Leung lacks the teaching of the type of pectin (high or low methyl ester pectin) that is used in the film and/or film composition of the instant invention. These deficiencies are cured by the teachings in Hoagland.

Hoagland teaches laminated film having one layer consisting of pectin and at least one chitosan film layer, and said pectin has a high molecular weight, large radius of gyration, a degree of methyl esterification is at least about 50%, and intrinsic viscosity is at least about 2.1 dl/g (claim 1 and 2). The laminates of this invention are useful for a number of applications including medicinal applications such as patches for the delivery of pharmaceuticals to skin. The laminates are taught to have a film thickness within the range of 0.10 to 0.15 mm. (See column 6, Lines 66-67).

***Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)***

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Leung et al. and Hoagland, because Leung teaches an orally consumable film made from pectin that is intended to deliver a bioactive agent and Hoagland teaches a film made of pectin and chitosan that is used to deliver a pharmaceutical (bioactive). It is recognized in the art that the components of film taught by Hoagland including chitosan can be orally consumed. The teaching of intrinsic viscosity of at least about 2.1 dl/g of Hoagland falls very well within the range of about 2.5 dl/g or less and about 1.8 dl/g or less of the instant claim since through routine experimentation of Hoagland's invention can lead an artisan arriving at the instant intrinsic viscosity being used. One would have been motivated to attain this viscosity because it would make a fast dissolving orally soluble film that would not be brittle and crack. I would have been obvious to include the methyl ester pectin taught by Hoagland in the invention of Leung et al. One would have been motivated to this since both references individually teach that pectin films are consumable friendly and effective in drug delivery. It would have been obvious to one of ordinary skill in the art at the time of the invention that the methyl ester pectin of Hoagland very well covers the high and low methyl ester pectin of the instant invention. The instant specification defines high methyl ester pectin as having higher than 50% degree of esterfication and low methyl ester pectin as having less than 50% degree of esterfication. With regard to the type of pectin used in the film composition Hoagland teaches at least about 50% methyl

esterfication. The phrase "at least about 50%" would suggest at least 50% and about 50%. About 50% would lead an artisan to films where the amount of methyl ester pectin is from 40 to about 50%. Therefore, in the absence of unexpected results Hoagland's teaching of at least 50% and suggests lower percents, e.g. 40- 49.9%. With regard to the film thickness Hoagland teaches a film that is falls within the range of 100 micrometers to 150 micrometers which necessarily encompasses the instant limitation **about 100 micrometers**. For the foregoing reasons the instant film would have been obvious to one of ordinary skill in the art at the time of the instant invention.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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